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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/700,340 | 11/03/2003 | Herath Mudiyanselage Athula Chandrasiri Herath | 2543-1-032 | 5254 |

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| EXAMINER | |
|---|---|
| HARRIS, ALANA M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1643 | |

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/700,340 | CHANDRASIRI HERATH, HERATH MUDIYANSELAGE | |
| | Examiner | Art Unit | |
| | Alana M. Harris, Ph.D. | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14 and 15, drawn to methods of diagnosis by protein measurement, classified in class 435, subclass 7.1.

II. Claims 11 and 12, drawn to a pharmaceutical composition comprising a Breast Cancer Associated Protein Isoform (BPI), classified in class 530, subclass 350. Claim 11 will be examined with this Group to the extent the said composition comprises a protein.

III. Claim 11, drawn to a pharmaceutical composition comprising a nucleic acid encoding a BPI, classified in class 536, subclass 23.5. Claim 11 will be examined with this Group to the extent the said composition comprises a nucleic acid.

IV. Claims 13 and 16-19, drawn to an antibody, a kit and a pharmaceutical composition comprising said antibody, classified in class 530, subclass 387.1.

V. Claim 20, drawn to a method of treatment using an antibody, classified in class 514, subclass 8.

VI. Claims 21, drawn to methods of treatment using nucleic acids that encode BPIs, classified in class 514, subclass 44.

VII. Claims 21, drawn to methods of treatment using BPIs, classified in class 436, subclass 86.

VIII. Claims 21 and 23, drawn to methods of treatment using nucleic acids, wherein the nucleic acid is a BPI antisense nucleic acid, classified in class 536, subclass 24.5.

IX. Claims 21 and 23, drawn to methods of treatment using nucleic acids, wherein the nucleic acid is a ribozyme, classified in class 424, subclass 94.1.

X. Claims 24-35, drawn to a method of screening for agents that interact with BPIs comprising contacting said BPI with a candidate agent, classified in class 436, subclass 8.

XI. Claims 36 and 37, drawn to a method of screening for screen or diagnosis of breast cancer comprising contacting an oligonucleotide probe to a nucleotide sequence encoding a BPI and detecting hybridization, classified in class 436, subclass 501.

XII. Claim 38, drawn to a method of modulating the activity of a BPI comprising administering an agent, classified in class 435, subclass 7.2.

XIII. Claim 39, drawn to a method of treating or preventing breast cancer comprising administering an agent that modulates the activity of a BPI, classified in class 424, subclass 184.1.

XIV. Claim 40, drawn to a method for identifying targets for therapeutic modulation of breast cancer, classified in class 424, subclass 130.1.

2. The inventions are distinct, each from the other for the following reasons. The methods of each of Groups I and V-XIV may each be practiced independently of on another. The proteins of Group II has uses other than in the method of Group I (*e.g.*, in affinity chromatography). The antibodies of Group IV are not needed to practice the methods of Group I. The nucleic acids, vectors, and host cells of Group III are not needed to practice the method of Group I. The proteins of Groups II are materially different from, and are therefore independent and distinct from, the antibodies of Group IV and the nucleic acids, vectors, and host cells of Group III. The proteins of Groups II and III are not needed to practice the methods of Groups VI, VIII, IX or XI. The antibodies of Group IV have uses other than the methods of Group V (*e.g.*, in affinity chromatography). The antibodies of Group IV are not needed to practice the methods of any one of Groups VI, VII, VIII, or IX. The antibodies of Group IV are materially different from, and are therefore independent and distinct from, the nucleic acids, vectors, and host cells of Group III. The nucleic acids, vectors, and host cells of Group III are not needed to practice the methods of Group V. The nucleic acids of Group III have uses other than the methods of Group IX (*e.g.*, in affinity chromatography).

Groups III, VI, VIII, IX and XI are drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than one individual, independent, and distinct nucleotide sequence in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996). This notice permits the examination of from one to ten independent and distinct nucleotide sequences in a single application based upon USPTO resources.

Should applicant elect a Group that claims or mentions more than one polynucleotide sequence, applicant is further required to select no more than ONE of the individual sequences for examination. The search of the no more than ONE selected sequence may include the complement of the selected sequence and, where appropriate, may include e subsequences within the selected sequence (*e.g.,* oligomeric probes and/or primers).

Gorups I, V, VII, X and XI-XIV are drawn to large numbers of polypeptides or mention or require the use of large numbers of polypeptides, as well as antibodies that bind said polypeptides. Should applicant elect a Group that claims or mentions more than one polypeptide sequence or an antibody, applicant is further required to elect one polypeptide sequence within the elected Group for examination on the merits.

To search any two groups as outlined above would create an undue burden for the U.S. PTO because the searches of the non-patent literature are not only non-overlapping to any appreciable extent, but are also divergent in nature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named

inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Reminder Regarding *In re Ochiai* and *In re Brouwer***

3. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner bee the patent issues. See MPEP § 804.01.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
28 September 2006